[Docket No. 39]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

BRISTOL-MYERS SQUIBB CO., Plaintiff and Counter-Defendant, v. XSPRAY PHARMA AB, Defendant and Counter-Claimant.	Civil No. 22-964 (RMB/MJS) **OPINION**

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BUMB, Chief District Judge

This matter comes before the Court upon the Motion for Judgment on the Pleadings by Defendant and Counter-Claimant Xspray Pharma AB ("Xspray"). [Docket No. 39.] However, the evidence Xspray relies upon in support of its motion is not properly before the Court at this early stage of litigation. And even if it were, such evidence is in direct conflict with the allegations set forth in the Amended Complaint, which states plausible claims of patent infringement by Plaintiff and Counter-Defendants Bristol Myers Squibb Company ("BMS"). Further, the Court is satisfied that the Amended Complaint puts Xspray on fair notice of the claims alleged against it, including the grounds upon which they rest in the context of this Hatch Waxman Act lawsuit. For these reasons, set forth below in greater detail, Xspray's motion shall be denied.

I. FACTUAL AND PROCEDURAL BACKGROUND

The Court sets forth only those facts necessary to its decision on the pending motion. BMS markets "dasatinib," a pharmaceutical drug sold under the trade name "Sprycel," used to treat chronic myeloid leukemia and Philadelphia chromosome-

positive acute lymphoblastic leukemia. [Docket No. 47 (hereafter, "BMS Brief"), at 5.] BMS asserts that Xspray's new drug infringes the following three patents it obtained to protect its significant investment in dasatinib: U.S. Patent Nos. 7,491,725 ("the '725 Patent"), 8,680,103 ("the '103 Patent"), and 8,242,270 ("the '270 Patent"). [BMS Brief at 2.] BMS recognizes, and Xspray does not dispute, that each of the patents it asserts in the present action are "directed to various crystalline forms of dasatinib."[1] [*Id.* at 5.] While the '725 and '103 Patents are both listed in the Orange Book for dasatinib/Sprycel, BMS also asserts infringement of the '270 Patent because it "describes and claims other crystalline forms of dasatinib." [*Id.*]

Xspray alleges that it "seeks to market a non-crystalline (i.e., 'amorphous') dasatinib product" under the trade name Dasynoc. [Docket No. 40 (hereafter, "Xspray Brief"), at 1.] On February 23, 2022, BMS initiated this suit against Xspray upon filing an initial complaint. [Docket No. 1.] Therein, BMS alleged that it received a letter from Xspray on or about January 13, 2022, notifying it that Xspray included a certification in its application pursuant to 21 U.S.C. § 355(b)(2)(A)(IV) (a

[1] More specifically, BMS acknowledges that:

> [t]he '725 Patent describes and claims crystalline dasatinib monohydrate, characterized by various properties associated with the crystalline form and method of making …
>
> [t]he '103 Patent describes and claims pharmaceutical compositions that include a crystalline monohydrate of dasatinib …
>
> [t]he '270 Patent describes and claims other crystalline forms of dasatinib, including ethanol solvates of dasatinib and neat forms of dasatinib, N-6 and T1H1-7.

[BMS Brief at 5 (citations omitted).]

"Paragraph IV Certification") that certain claims of BMS's '725 and '103 patents are invalid or will not be infringed by Xspray's new drug. [*Id.* ¶ 25.] BMS also alleged in its initial complaint that the Paragraph IV Certification received from Xspray notified it that Xspray had sought approval from the U.S. Food and Drug Administration ("FDA") "to launch a generic version of BMS's Sprycel[] (dasatinib) with 100mg dosage strength." [BMS Brief at 6.] Xspray contends that it applied for a New Drug Application pursuant to 21 U.S.C. § 355(b)(2) ("NDA"), commonly referred to as a Section 505(b)(2) application, and not an Abbreviated New Drug Application under 21 U.S.C. § 355(j) ("ANDA") because it intends to market a new and improved drug, not merely a "carbon-copy 'generic version'" of BMS's drug. [Xspray Brief at 2–3.]

BMS received a second Paragraph IV Certification from Xspray on May 17, 2022, informing it that Xspray had filed an amendment to its NDA to include five additional dosage strengths: 15 mg, 36 mg, 50 mg, 57 mg, and 70 mg. [BMS Brief at 6.] Upon receipt of the second Paragraph IV Certification from Xspray, BMS initiated another federal infringement lawsuit challenging, in part, these new dosage strengths. [Civil No. 22-4328, Docket No. 1.] BMS filed an Amended Complaint in that second-filed action on August 2, 2022, asserting infringement of the '270 Patent in addition to the '725 Patent and the '103 Patents (the two Orange Book-listed patents asserted in BMS's initial complaint). [*Id.*, Docket No. 6 (hereafter, "Amended Complaint").] On October 19, 2022, as agreed by the parties, the Court consolidated both actions, designating Civil No. 22-964 as the lead case. [*Id.*, Docket

No. 28.] The Amended Complaint alleges that "Xspray seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Xspray NDA Products prior to the expiration" of the three patents asserted by BMS. [Amended Complaint ¶¶ 32 (the '725 Patent), 44 (the '103 Patent), 56 (the '270 Patent).]

On September 23, 2022, Xspray filed the Motion for Judgment on the Pleadings, which is now ripe for adjudication. [Docket No. 39.] Xspray argues that "while DASYNOC[] includes no longer patented dasatinib, it is not covered by BMS's narrow patents on specific crystalline forms." [Xspray Brief at 2.] According to Xspray, the litigation need not proceed any further because [redacted] [*Id.*]

In opposition, BMS argues that the Court should deny Xspray's motion because the pleading standard for this Hatch-Waxman action has already been met given BMS's specific allegations "that Xspray filed an NDA that relies on BMS's application for Sprycel[]." [BMS Brief at 2.] BMS also argues that the general references to Xspray's NDA in the Amended Complaint, including the fact that it was filed, "do not incorporate the entire NDA" for purposes of deciding the pending motion for judgment on the pleadings. [*Id.* at 3.] Further, BMS argues that even if the Court were to rely on Xspray's NDA at this stage of litigation [redacted]

[redacted] [*Id.* at 4; *see also* [redacted] According to BMS, a drug that permits these crystalline dasatinib forms "falls squarely within, and infringes, the asserted claims." [BMS Brief at 4.]

II. JURISDICTION AND VENUE

This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Defendant Xspray is a foreign corporation not residing in any United States district, and thus, may be sued in any federal judicial district. *Id.* § 1391(c)(3). Venue is proper because BMS has alleged that Xspray has committed acts of infringement by filing the Xspray NDA intending to market its NDA product nationwide, including within New Jersey. *Id.* §§ 1391(b), 1400(b). Not only has Xspray never contested venue, but it also filed counterclaims against BMS for declaratory judgment – alleging invalidity, non-infringement, and no injunctive remedy for the '725 Patent and the '103 Patent – in this District. [Civil No. 22-4328, Docket No. 14, at 38–43.]

III. LEGAL STANDARD

The Third Circuit made clear that "[a] motion for judgment on the pleadings under Rule 12(c) 'is analyzed under the same standards that apply to a Rule 12(b)(6) motion.'" *Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019) (quoting *Revell v. Port Auth. of N.Y. & N.J.*, 598 F.3d 128, 134 (3d Cir. 2010)). Thus, the Court must view the facts pled and draw any inference therefrom "in the light most favorable to the nonmoving party," and may not grant any such

motion unless the moving party "clearly establishes that no material issue of fact remains to be resolved and that [it] is entitled to judgment as a matter of law." *Id.* (citations omitted). As with a 12(b)(6) motion to dismiss, to survive a Rule 12(c) motion the allegations set forth in the Amended Complaint "require[] more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted).

The general rule for reviewing a motion to dismiss or Rule 12(c) motion for judgment on the pleadings is that district courts "may not consider matters extraneous to the pleadings." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). However, a well-known exception exists for a "document *integral to or explicitly relied* upon in the complaint," which may be considered "without converting the motion … into one for summary judgment." *Id.* (emphasis in original). Like consideration of a motion to dismiss, the relevant inquiry for the Court to consider here asks ""not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim." *Twombly*, 550 U.S. at 563, n.8 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). The pending motion should be granted only if BMS's Amended Complaint fails to plead "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. Finally, the Federal Circuit has explained that while a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level," at the same time, "[s]pecific facts are not necessary; the statement need only 'give the defendant fair notice of what the … claim is and the grounds upon which it rests.'"

Bot M8 LLC v. Sony Corp. of Am., 4 F.4th 1342, 1353 (Fed. Cir. 2021) (first quoting *Twombly*, 550 U.S. at 555; then quoting *Erickson v. Pardus*, 551 U.S. 89, 93 (2007)).

IV. ANALYSIS

A. Xspray's NDA is Not Properly Before the Court in Deciding the Pending Motion for Judgment on the Pleadings

As an initial matter, the Court notes that Xspray's pending motion foundationally relies upon the contents of its NDA and not the sufficiency of BMS's claims as set forth in the Amended Complaint. The Federal Circuit has found that in some instances, district courts may consider certain documents beyond the pleadings in resolving a motion for judgment on the pleadings, including official patent filings with the FDA. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1378, n.5 (Fed. Cir. 2012) (explaining that the district court could consider the ANDA and certain other FDA filings in deciding a motion to dismiss because such documents were referenced and relied upon in the underlying complaints and "the parties do not dispute the authenticity of the documents that were before court"). Indeed, there is no dispute regarding the authenticity of Xspray's NDA here. Instead, BMS accuses Xspray of relying upon "cherry-picked portions of its NDA" in support of the pending motion, which cites [redacted] while the full NDA produced by Xspray to date "includes at least [redacted] spanning at least [redacted] [BMS Brief at 3, 14.]

However, in other instances, courts in this Circuit have concluded that when such FDA filings are only referred to generally by a plaintiff claiming patent

infringement and not explicitly relied upon in the underlying complaint, such documents should not be considered at this early stage of litigation. *See Par Pharm., Inc. v. Hospira, Inc.*, Civ. No. 17-944, 2018 WL 3343238, at *2 (D. Del. May 11, 2018) (concluding that the court could not review an ANDA filing in deciding a motion to dismiss since the references in the complaint were "limited to the fact of the ANDA's filing and to summarize its contents as described in the Paragraph IV notice letter"); *see also Corcept Therapeutics, Inc. v. Teva Pharms. USA*, Inc., Civ. No. 18-3632, 2018 WL 5263278, at *3, n.3 (D.N.J. Oct. 23, 2018) (declining to consider an ANDA filing in deciding a motion to dismiss since the plaintiff "neither attached" the ANDA to an amended complaint "nor relied on it directly"); *Cima Labs, Inc. v. Actavis Grp. HF*, Civ. No. 06-1970, 2007 WL 1672229, at *4 (D.N.J. June 7, 2007) (declining to consider an ANDA in resolving a Rule 12(b)(6) motion "because Plaintiffs did not explicitly rely on the ANDA document").

BMS argues that it "did not rely on ***any*** specific portion of Xspray's NDA in its Amended Complaint."[2] [BMS Brief at 15 (emphasis in original).] Having

[2] In their supporting briefs, the parties dispute the adequacy of the confidential access provided to BMS after it received Xspray's two Paragraph IV Certification letters as required under the Hatch Waxman Act. BMS alleges that Xspray "refused to allow BMS's in-house counsel" access to "any of Xspray's confidential information." [BMS Brief at 6.] At the same time, Xspray contends that BMS did not accept an offer to give "BMS's outside counsel access to Xspray's confidential NDA itself," and instead "demanded a battery of sample that Xspray did not have and a drug master file that Xspray does not own." [Xspray Brief at 14.] In this Court's view, this breakdown in communications between the parties regarding BMS's pre-discovery access to Xspray's NDA is yet another reason why the pending motion should be denied so the record may be further developed through fact discovery.

carefully reviewed the Amended Complaint and its references to Xspray's NDA, the Court agrees. Indeed, BMS did not attached Xspray's NDA to its Amended Complaint nor its initial complaints for that matter. BMS also did not explicitly cite any of the specific sections or other contents of the NDA in its Amended Complaint, but rather, referred to it only generally. In any event, BMS did not rely upon any of the specific pages and documents from the nearly 60,000-page NDA that Xspray now urges the Court to consider as evidence of non-infringement prior to any fact discovery. Like the plaintiff in *Par Pharm.*, here, BMS referenced the NDA in the Amended Complaint to demonstrate the fact that it was filed (and amended) by Xspray, that infringement will occur if it is approved, and to summarize its contents. [*See, e.g.*, Amended Complaint ¶¶ 5–6, 26, 35–39.] Thus, the Court finds that the NDA is not properly before it for purposes of deciding the pending motion.

B. The Amended Complaint States Plausible Claims of Patent Infringement

BMS argues that its Amended Complaint properly pleads claims of patent infringement by alleging that on May 18, 2022, Xspray sent it a letter "stating that Xspray had included [the Paragraph IV Certification] in the Xspray NDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(IV), that, inter alia, certain claims of the '725 and '103 Patents are either invalid or will not be infringed by the commercial manufacture, use, sale, offer to sell or importation into the United States of the Xspray NDA Products." [BMS Brief at 9 (quoting Amended Complaint ¶ 28).] The Amended Complaint also specifically alleges that "Xspray intends to engage in the commercial

manufacture, use, offer for sale, and/or sale of the Xspray NDA Products prior to the expiration of the '725, '103 and '270 patents." [Amended Complaint ¶ 28.] As previously noted, the Amended Complaint also expressly alleges that "Xspray seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Xspray NDA Products prior to the expiration" of the patents asserted. [Amended Complaint ¶¶ 32 (the '725 Patent), 44 (the '103 Patent), 56 (the '270 Patent).]

District courts have squarely addressed the challenge Xspray now brings here regarding the sufficiency of the Amended Complaint, which is that BMS must more specifically plead how the infringement it alleges will occur. *See Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 330 (D. Del. 2019) ("Defendant's position is that while the Hatch-Waxman Act creates subject matter jurisdiction over the 'artificial act of infringement' of filing a paper NDA (or ANDA), actual infringement still must be pled with particularity."). The *Belcher Pharms.* Court provided the following rationale for rejecting this argument:

> [i]n the Court's view, both the language and the purpose of the Hatch-Waxman Act establish that a plaintiff in receipt of a paragraph IV certification providing notice of the filing of an ANDA (or, as here, a paper NDA) relating to one of the plaintiff's Orange Book-listed patents may state a claim for infringement by alleging its interest in the patent, its receipt of the paragraph IV certification, the filing of the ANDA or NDA, and its contention that the defendant's proposed product will infringe. Under the Act, filing an ANDA or paper NDA constitutes an artificial but justiciable act of patent infringement.

Id. at 330–31. The *Belcher Pharms.* Court then went on the explain that the purpose behind the Hatch-Waxman Act, as expressed by the Supreme Court in *Eli Lilly & Co.*

v. Medtronic, Inc., 496 U.S. 661 (1990), was "to facilitate the speedy and cost-effective entrance of generic drug to the market," and that such "purpose is advanced by allowing plaintiffs in this type of case to rely on the sufficiency of pleading the artificial act of infringement, allowing the particularized theory of infringement to be developed through discovery and other phases of the case." *Id.* at 331.

Here, this Court agrees with *Belcher Pharms.* and finds that in this context, BMS's Amended Complaint allows reasonable inferences to be drawn that Xspray is liable for the infringement alleged. Most importantly, the Court finds that the BMS's pleadings – initiating a Hatch Waxman lawsuit, but only after Xspray notified BMS that it made certain Paragraph IV Certifications to the FDA regarding potential infringement of BMS's Orange Book-listed patents – fairly put Xspray on notice of the claims asserted by BMS in the Amended Complaint and the grounds upon which they rest. Thus, the Court also agrees with the ruling in *Belcher Pharms.* that when a plaintiff pleads an artificial or technical claim of patent infringement under the Hatch Waxman Act, the complaint "complies with the requirements of *Iqbal* and *Twombly* as applied to [this] unique context." *Id.* at 332; *see also Shire LLC v. Mylan Inc.*, Civ. No. 12-638, 2012 WL 2072665, at *2 (D.N.J. June 7, 2012) ("While the filing of an ANDA may be often called a 'technical' act of infringement under § 271(e)(2), it is by statute an act of infringement, nonetheless.") Thus, the Court finds that the Amended Complaint states plausible claims of patent infringement.

C. Even if the Court Considered the NDA, It Raises Material Issues of Fact Regarding Whether Crystalline Forms of Dasatinib Are Actually Permitted in Xspray's New Drug

Finally, even if Xspray's NDA were integral to or explicitly relied upon in BMS's Amended Complaint, the Court could not rely on the portions Xspray argues prove non-infringement. This would be in direct conflict with other portions of the NDA, which BMS argues show that infringing levels of crystalline dasatinib is permitted in Xspray's new drug.

Appended to the BMS Brief is [redacted] [Docket No. 47-1.] [redacted] and the Court finds that BMS has a legitimate concern regarding permitted crystalline forms, namely [redacted] [*Id.*; BMS Brief at 21.] The Court also finds convincing BMS's concern that [redacted] [BMS Brief at 21–22 (citing Exs. 5, 6)..] In any event, whether the NDA actually permits any of BMS's patented crystalline forms of dasatinib is clearly a question of material fact that remains. Thus, the Court must deny the pending motion.

Relatedly, the Third Circuit recently clarified that "[w]hen the truth of facts in an 'integral' document are contested by the well-pleaded facts of a complaint, the

facts in the complaint must prevail." *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022). The Circuit explained the guidance that district courts must accept factual assertions in a complaint as true remains "even if it strikes a savvy judge that actual proof of those facts alleged is improbable and that a recovery is very remote and unlikely." *Id.* (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 213 (3d Cir. 2009)). This is because "[t]he proper place to resolve factual disputes is … on a motion for summary judgment." *Id.* (citing *Flora v. Cnty. of Luzerne*, 776 F.3d 169, 175–76, n.9 (3d Cir. 2015). At most, Xspray's motion relies upon the truth of certain contents in its NDA, which are in direct conflict with the allegations set forth in the Amended Complaint. Thus, the allegations in the Amended Complaint must prevail.

Xspray raises a good point that sometimes, "Hatch-Waxman cases *do* get dismissed, and that they can get dismissed by considering the ANDA or NDA." [Docket No. 50.] For example, in *Astrazeneca*, the Federal Circuit affirmed the dismissal of a complaint based on the defendant's ANDA filings. *AstraZeneca Pharms.*, 669 F.3d at 1381. However, *Astrazeneca* involved what is referred to as a "section viii" statement in the Hatch-Waxman context, a mechanism through which a generic filer may identify and file for FDA approval to market a generic drug for particular *unpatented* uses. The Federal Circuit reasoned in *Astrazeneca* that "a patented method of using a drug can only be infringed … by filing an ANDA that seeks approval to market the drug for that use. Thus, an ANDA seeking to market a drug not covered by a composition patent for unpatented methods of treatment

cannot infringe." *Id.* at 1379. Since the plaintiff never alleged that the challenged ANDA sought FDA approval for any patented use, the underlying complaint failed to state a claim. *Id.*

Xspray cites other cases where based on the specific facts alleged, "the pleadings [fell] short." [Xspray Brief at 21 (collecting cases).] For example, Xspray cites *Otsuka Pharm. Co. v. Zydus Pharms. USA*, but in that case dismissal of the underlying complaint was affirmed because "[e]ach [d]efendants' ANDA … included a "section viii" statement, certifying that the applicant would not see approval for any indications or uses asserted to be covered" by the patent at issue. 151 F. Supp. 3d 515, 518 (D.N.J. Oct. 13, 2015). Another case cited by Xspray, *Cumberland Pharms. Inc. v. InnoPharma, Inc.*, is also clearly distinguishable because there, the district court could determine from the face of the complaint that it failed to state a plausible claim for relief. Civ. No. 12-618, 2013 WL 5945794, at *2 (D. Del. Nov. 1, 2013) (explaining that "all claims of the patent-in-suit cover only a formulation 'free from a chelating agent,' yet the [c]omplaint alleges that InnoPharma's product contains EDTA, which is 'a chelating agent'") (citations omitted). Xspray also cites *Celgene Crop. v. Mylan Pharms. Inc.* for the broad proposition that "[j]udgment as a matter of law is still appropriate if the pleadings fall short. [Xspray Brief at 21.] But there, the underlying complaint was dismissed because the pleadings failed to show that venue was properly imputed under an alter-ego or veil piercing theory. 17 F.4th 1111, 1126 (Fed. Cir. 2021).

Put simply, context matters. None of the cases Xspray cites establishes that a motion for judgment on the pleadings may be granted based upon the contents of an NDA, which is neither integral to nor specifically referenced in an Amended Complaint, particularly when such contents are in direct conflict with the allegations and claims set forth in the Amended Complaint, as well as other parts and documents of the same NDA. In any event, the parties' arguments make clear that Xspray is on fair notice of the allegations of patent infringement being made against it, including whether its new drug includes any of the crystalline forms of dasatinib claimed under the '725, '103, or '270 Patents. The Federal Circuit has cautioned that in cases such as this "where the subject matter is a compound capable of existing in multiple crystalline forms, or mixtures thereof, the ultimate question of infringement is not so simple." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). This is consistent with the Court's ruling here that additional discovery is warranted and Xspray's motion must be denied

V. CONCLUSION

It is not proper for the Court to consider the NDA when it is neither integral to nor referenced in BMS's Amended Complaint. Even if the Court were to consider the NDA, such evidence is not determinative of the conflicting, factual allegations set forth in the Amended Complaint that Xspray's new drug will infringe the '725 Patent, the '103 Patent, and the '270 Patent. At best, the record presently before the Court includes conflicting factual allegations. Considering those allegations in the light most favorable to the non-movant and the contents of the Amended Complaint,

the pending motion shall be denied. An accompanying Order of today's date shall issue.

April 25, 2023
Date

s/Renée Marie Bumb
Renee Marie Bumb
Chief District Judge